

DETAILED ACTION

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments.

Election/Restrictions

Claims 70-72, 74-77, 79-98 and 130-162 are directed to an allowable process. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 99-128, directed to the process of making an adenovirus composition, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on June 22, 2004 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information

submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The information disclosure statement (IDS) submitted on October 22, 2008 was filed after the mailing date of the non-final Office action on February 22, 2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Terminal Disclaimer

The terminal disclaimers filed on October 10th and 15th are disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patents 6,727,907 and 7,125,706 have been reviewed and are accepted. The terminal disclaimer has been recorded. Since no restriction was made involving a product similar to that claimed in patents '907 and '706, the claimed methods of the instant application were viewed as being obvious over these products which raised additional Obviousness-type Double Patenting Rejections. Therefore, applicants were informed on October 14th that Terminal Disclaimers would be required (see interview summary).

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: the prior art fails to teach the production of adenovirus (or any other related virus) through perfusion or fed-batch processes, which may or may not include purifying the adenovirus to a level of purity in which the contaminating nucleic acid is less than 400 pg per 10¹⁰ pfu of

adenovirus and greater than or equal to about 60 pg per 10^{10} pfu of adenovirus or a contaminating nucleic acid concentration less than 0.8 ng/ml or less than 0.2 ng/ml.

Support for these amounts of contaminating nucleic acids can be found in tables 10 and 11 when both are analyzed separately and when combining the information presented.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Summary

Claims 70-72, 74-77, 79-128 and 130-162 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648